Influence of maternal confidence on exclusive breastfeeding until six months of age: a systematic review

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> **Abstract** Breastfeeding is a practice directly related to the health of the mother and especially the baby. Despite being a natural process, many mothers report difficulties with breastfeeding. This study aimed to seek scientific evidence on the issue: "Can a mother with more confidence in breastfeeding exclusively breastfeed her baby for 06 months?". We conducted a systematic review with a search in five electronic databases, and included four cohort studies for evaluation. We conducted a qualitative analysis of the results, considering the methodological differences and lack of data, and were unable to perform meta-analysis. Confidence in breastfeeding was evaluated by using the Breastfeeding Self-Efficacy Scale. The studies analyzed showed statistically significant association between the practice of breastfeed and confidence in breastfeeding. The application of a scale to evaluate trust and identify mothers at risk for early weaning appeared to be a reliable measurement tool, capable of facilitating action planning by health professionals. The evidence showed association between mothers with higher levels of confidence in breastfeeding and exclusive breastfeeding for 6 months, but these results could not be generalized because of the heterogeneity of the population.

Key words Exclusive breastfeeding, Self-efficacy, Breastfeeding, Breastfeeding self-efficacy scale, Breastfeeding self-efficacy scale-short form

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Introduction

Breastfeeding is a practice of great importance to both the mother and baby, because both derive health and other benefits from it. Breastfeeding promotes involution of the uterus in the postpartum period, reduces the chance of breast, ovarian and uterine cancer, minimizes the child's consumption of industrialized products such as food and medication to treat possible illnesses. In relation to the baby, it promotes correct development of the face, phonation, breathing and swallowing, and prevents infant morbidity and mortality. Some authors have associated breastfeeding with better intellectual development, levels of schooling and income in adulthood¹⁻⁷.

Both Brazilian and International Health Agencies recommend that breastfeeding should be a source of exclusive feeding for infants; that is, without water and other liquids, up to 6 months of age. After this period, the baby's diet can be supplemented with other solid and liquid foods, maintaining breastfeeding up to two years of age or older8-11. Even when starting with exclusive breastfeeding after childbirth, many mothers abandon, or complement this practice in the first few weeks. This is due to several factors, such as: the baby's difficulty with sucking the breast; flat or inverted and / or sore nipples and insufficient milk production². In addition, the following factors should be mentioned: influence of the mother's emotional status; socioeconomic condition; educational level; family incentive; real intention to breastfeed, and the mother or pregnant woman's lack of knowledge about the subject^{3,6,12}.

Although breastfeeding is a natural and healthy practice, many women report difficulties; these are influenced by several factors, among them: the mother's self-confidence. Recently published studies have described that mothers with lower self-confidence breastfeed for less time^{13,14}.

According to Bandura¹⁵, self-confidence is personal confidence in effectively accomplishing a task or achieving a particular goal. In relation to breastfeeding, this characteristic can generate "a woman's confidence or positive expectation regarding her knowledge and skills to breastfeed her baby successfully"¹⁶⁻²¹. Based on this information, an instrument for the assessment of maternal self-confidence, entitled the Breastfeeding Self-Efficacy Scale (BSES), was developed and validated by Dennis and Faux¹⁶. The scale is based on four sources of information: personal experience - positive and / or negative - about previous

breastfeeding; observation of other experiences talking to mothers who have already breastfeed; verbal persuasion - encouragement and encouragement of people close to her and of connoisseurs on the subject; and, finally, emotional and physiological factors - capable of both positively and negatively influencing performance of the practice^{6,20,22,23}. The scale was translated and validated in several countries, including Brazil, in two models: 1) Breastfeeding Self-Efficacy Scale (BSES)⁴, containing 33 items, and 2) Breastfeeding Self- Efficacy Scale- Short Form (BSES-SF), containing 14 items²⁴. The score can vary from 33 to 165 points in the original scale¹⁶, and from 14 to 70¹⁷ in the short form, indicating that the higher the score, the greater the maternal self-confidence in breastfeeding, thus enabling health professionals to recognize situations in which the woman has less confidence, and intervene early to avoid premature weaning^{6,16,17}.

Self-confidence in breastfeeding was observed to have been reported as a predictive factor for the duration and exclusivity of the practice of breastfeeding^{3,21,25,26}, and that the use of BSES was an internationally applicable, reliable and valid measure to assist the health professionals in the care of breastfeeding women⁴. However, up to now, there is no systematic review on breastfeeding self-confidence and the practice of Exclusive Breastfeeding (SMA) at 6 months of the baby's life.

Thus, the aim of this systematic review was to evaluate the scientific evidence related to the following question: "Can a mother with more confidence in breastfeeding, exclusively breastfeed her baby for 6 months?" The PICO technique was used (P = population, control and O = "outcome" that means outcome) for the formulation of the research question, being: (1) Population: pregnant women and postpartum women of first gestation or not; (2) Intervention / exposure to risk factors: Maternal self-confidence in breastfeeding assessed by using the BSES and BSES-SF scales; (3) Outcome: Exclusive breastfeeding for up to 6 months.

Methodology

Longitudinal studies (cohort, case-control and clinical trials) were sought, with women and pregnant women of all ages who reported on the practice of exclusive breastfeeding at 6 months of age, and maternal self-confidence in breastfeeding. Selection of the studies was carried out in

two phases: (1) screening of abstracts and titles and (2) reading of the selected full texts to determine the final set of the sample.

The question asked was: "Can a woman (pregnant or puerpera) with greater self-confidence in breastfeeding, exclusively breastfeed her baby for up to 6 months or longer?"

Search strategy

Inclusion criteria for this systematic review were: longitudinal studies, clinical trials, control trials; studies published between January 1, 1999 (date of first publication on Breastfeeding Self-Efficacy Scale) and September 1, 2015; application of the BSES scale (original and reduced); studies that presented follow-up of breastfeeding for 6 months or longer; that analyzed the specific scale and other variables; found only in indexed journals; with results; (primiparous or not), regardless of age or race, and published in Portuguese, English or Spanish.

The articles search was carried out with the participation of two independent reviewers (ISR, NBR), in 5 databases: PubMed Medline (http://www/pubmed.gov); Web of Science (http://www.isiknowledge.com); Cochrane Library (http://www.cochrane.org/index.htm); US National Institutes of Health (http://www.clinicaltrials.gov) and Virtual Health Library (Bireme, Latin America) (http://www.bireme.br).

The key words used in search strategy performed in MEDLINE, Web of Science and Cochrane Library were as follows: ("breast feeding" [OR] breastfeed * OR breastfeeding * OR breastfeeding oR breast feed OR breast feeding OR breastfeeding self-efficacy scale OR breast feeding self- feeding confidence OR BSES-SF) NOT ("animals" [Mesh] NOT "man" [Mesh])).

In the US National Institutions of Health, the following keywords were used: "breast feeding", "breast feeding self-efficacy scale". While in Bireme, the combination used was: "breastfeeding", "self-efficacy", "questionnaire", "pregnancy", "female", and "breastfeeding".

The online search resulted in 3,810 titles. The ENDNOTE Web program (http://www.myend-noteweb.com/) was used to organize the studies. After the duplicate references were removed, the titles /abstracts of 3,398 publications were eval-

uated. Approximately 10% of these were independently read by three reviewers to determine the inter-examiner agreement (Kappa: 0.71). Disagreements were resolved by consensus. After reading, 3,271 records were excluded by title / abstract as they did not meet the established inclusion criteria.

Exclusion criteria were: exclusive breastfeeding before 6 months; studies that did not present the BSES and / or BSES-SF scales; outcomes that did not compare the score with SMA at 6 months; studies with methodological designs that differed from longitudinal (cross-sectional, laboratory, reports and case series, opinion); published before 1999; animals and / or men; without results or unpublished.

We selected 127 publications for full text analysis (Figure 1). No clinical trials were found. A calibration exercise was carried out with six studies, for the purpose of enabling the two independent reviewers (ISR, NBR) to subsequently read all the complete texts.

Data extraction

Data extraction was performed by the two reviewers (Figure 1), of which the outcome of interest was: mothers who presented high scores on the application of BSES and / or BSES-SF; that is, greater self-confidence, thus being able to exclusively breastfeed for a longer time (in the follow-up of 06 months postpartum) than those with lower scores.

Evaluation of methodological quality

For the methodological quality evaluation, the Newcastle-Ottawa Scale²⁷ was used for cohort studies (Table 1), modified according to the needs presented by the present study. The scale was proposed by Wells et al.27 for evaluating non-randomized studies (cohort and control case studies) and consists of 3 dimensions: criteria for sample selection, comparability and results. Each dimension is composed of eight items that present several answer?/response options. To perform the evaluation, a star system was used, in which a star corresponded to a point. Each item received one star, except for the item "comparability" that could receive two. Thus the score ranged from zero to nine points, considering lower or higher quality, respectively²⁷. Disagreements were resolved by consensus.

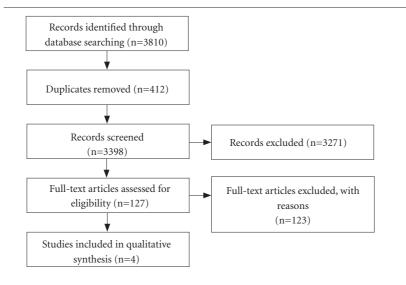


Figure 1. PRIMA Flow Diagram.

Table 1. Quality evaluation criteria used for cohort studies through a modified version of the Newcastle-Ottawa scale.

Criteria	McCarter-Spaulding& Gore, 2009	Bosnjak et al., 2012	Ip et al., 2012	Henshaw et al., 2015
Criteria for sample selection				
1) Representativeness of exposed cohort (Self-				
confidence in breastfeeding BSES)				
a) A truly representative sample *		a (*)	a (*)	
b) Somewhat representative of the average community *	<i>b</i> (*)			b (*)
c) Potential for selection biases or does not have satisfactory requirements in part (a)				
d) no description of the derivation of the cohort				
2) Selection of the non exposed cohort				
a) Drawn from the same community as the exposed cohort *	a (*)	a (*)	a (*)	a (*)
b) Drawn from a different source				
c) No description of the derivation of the non- exposed cohort				
3) Ascertainment of Exposure				
a) Secure record *				
b) Structured interview with calibrated researcher *				
c) Self report	С	С	с	с
d) No description				
4) Demonstration that self-confidence in				
breastfeeding and the association of breastfeeding				
were present at the beginning of the study				
a) Yes	a (*)	a (*)	a (*)	a (*)
b) No				

Table 1. Quality evaluation criteria used for cohort studies through a modified version of the Newcastle-Ottawa scale.

Criteria	McCarter-Spaulding& Gore, 2009	Bosnjak et al., 2012	Ip et al., 2012	Henshaw et al., 2015
Comparabilidade				
1) Comparability of cohorts on the basis of design or analysis				
a) Exposure of interest (BSES and breastfeeding) is adjusted to one confounding factor *	a (*)	a (*)	a (*)	a (*)
b) Exposure of interest (BSES and breastfeeding) is adjusted for two or more confounders **				
(c) Description related to adjustment analysis for confounding factors				
Outcome				
1) Assessment of outcome				
a) independent blind evaluation *				
b) self-report	b	b	b	b
c) no description				
2) Was Follow-Up Long Enough for Outcomes to				
Occur				
a) Yes (follow-up period of 06 months)*	a (*)	a (*)	a (*)	a (*)
b) No				
3) Adequacy of follow-up of cohorts				
a) Complete follow-up - all subjects answered *				
b) Individuals lost to follow-up unlikely to introduce bias - small number lost ($< 10\%$)*	<i>b</i> (*)	<i>b</i> (*)	b (*)	
c) Track rate <30% and no description of those				С
individual lost				
d) No declaration				
Total of stars	6/9	6/9	6/9	5/9

One point (*); two points (**); Maximum score: 9 points.

Data synthesis

The studies presented heterogeneous information, since they varied according to the time interval of the scale (from 48 hours to one week postpartum) and / or some difference in the sample characteristics (application in primiparous mothers or in a specific ethnic group). However, the results of the studies were not quantitatively evaluated, because there were not enough data to be grouped, so it was not possible to perform the meta-analysis (Table 2).

Results

Characteristics of the studies

Among the 127 papers selected for the full text analysis, 04 cohort studies conducted in the following countries: the United States^{19,28}, China²⁹ and Croatia²⁶, were included in the present systematic review. All the studies, in some way, related the mother's self-confidence (measured by the application of BSES or BSES-SF) to the duration of exclusive breastfeeding at 06 months of age. Breastfeeding was evaluated longitudinally from birth and at specific time intervals until the end of the study in which the result was obtained.

Table 2. Cohort studies included in the systematic review, according to their quality index.

Author/ year	Country	Initial Sample	Time of application BSES / BSES-SF	Mean Scale Score	Follow-up	No of women who exclusively breastfed up to 06 months	Outcome of Quality **	Quality **
Bosnjak et al., 2012	Croatia	236	Before discharge from hospital	55	06 months	39	Yes	6/9
Ip et al., 2012	China	176	48-72 hours postpartum	41.1	06 months	24	Yes	6/9
McCarter-Spaulding& Gore, 2009 USA	USA	125	2-3 days postpartum	51,86	06 months	01	Yes	6/9
Henshaw et al., 2015	USA	142	2 days postpartum	Not reported	06 months	87	Yes	5/9
* "Mise com major autoconfiance amenteram nor maje temno? ** Don	entaram nor mais tem	A ** Dontila	firação máxima: 0 pontos					

"Mães com maior autoconfiança, amamentaram por mais tempo? ** Pontuação máxima: 9 ponto

Qualitative Analysis

Factors related to the duration of exclusive breastfeeding

According to the studies analyzed, one of the main factors related to the duration of exclusive breastfeeding was maternal self-confidence in breastfeeding. The following factors were also cited as important factors: psychological adjustment; body image; ethnicity and / or race; mother's intention to breastfeed; age; educational level; if employed; if she lived in her own household, or lived with her family and / or friends; in addition to emotional factors or depressive symptoms; a sense of maternal coherence (the mother's ability to deal with difficult or unexpected situations in relation to breastfeeding), and whether the mothers were primiparous or multiparous^{19,26,28,29}.

BSES / BSES-SF score and duration of exclusive breastfeeding

All the studies emphasized the information that mothers who presented the highest scores in the BSES / BSES-SF application, exclusively breastfed for a longer period of time (at 6 months postpartum follow-up). However, some studies have shown possible flaws in this regard, since there were relative differences in the scores presented by primiparous and multiparous women. It is believed that Those who already had more than one child were believed to have previous experience with breastfeeding, and therefore, their response to confidence in breastfeeding consequently differed from that of those who did not have previous experience, since it was their first pregnancy^{19,26,29}.

Quality assessment

The quality was evaluated using the modified Newcastle-Ottawa scale, and scored between 5 and 6 (with a maximum of 9 points). The main deficiencies were related to the data collection process, because the studies did not present the same pattern in the analyzed population; considering that some were conducted only with primiparous mothers²⁸ while others had samples that also included multiparous mothers^{19,26,29}. All were conducted through self-reports; that is, self-administered questionnaires.

Results of the studies relative to the self-confidence values and practice of exclusive breastfeeding at 06 months

The analysis of the self-confidence values presented by the mothers, according to the scores obtained in the scales applied in the studies, showed significant differences in score, since there was no standardization of the type of scale used. Thus, the study that used the scale in its complete form did not present application values of the BSES scale, as this was not the aim of the cited study²⁸. Nevertheless, the studies that presented application of the scale in its reduced form showed the following mean values: 41.129; 51.919 and 5526. Among the studies, 03 showed that there was a significant relationship between the score obtained and the duration of exclusive breastfeeding, with maternal efficacy increasing with the duration of SMA in 06 months. Only the study by Ip et al.29 did not clearly show the association value (p value), but reported that the association was significant.

Relationship between demographic factors and duration of exclusive breastfeeding

In the study by Bosnjacket al.²⁶, demographic factors; maternal age, and high schooling were positively associated with the time of exclusive breastfeeding. In this study, the association between BSES-SF and the women's ability to deal with stressful situations during the breastfeeding period (SOC) was also made, since mothers with positive SOCs constructed or improved their self-efficacy in breastfeeding.

Whereas, Ip et al.²⁹ and Henshaw et al.²⁸ did not mention this relationship in their studies, however, the latter demonstrated that high BSES scores were related to the lower symptoms of depression and greater emotional adjustment in mothers in the postpartum period.

Moreover, McCarter-Spaulding and Gore¹⁹ reported that there was no difference between the score values and the maternal age; marital status, and family income of the mothers. However, there were differences based on ethnicity, in which African American women reached a lower values than those who did not consider themselves African.

Discussion

Aims and Particular Factors related to exclusive breastfeeding involved in the studies analyzed

The studies presented heterogeneous aims, however, all of them evaluated the practice of breastfeeding and applied one of the BSES / BSES-SF scales. Bosnjack et al.²⁶ and Ip et al.²⁹ aimed to translate and validate the reduced form of the scale in women from Croatia and Hong Kong in Japan, respectively, in addition to assessing their ability to identify mothers susceptible to practice early weaning. Differently, Henshaw et al.²⁸ sought to prospectively evaluate the relationship between mood and breastfeeding outcomes in primiparous mothers. McCarter-Spaulding and Gore¹⁹ examined the psychometric properties of BSES-SF in black women in the United States.

in view of the foregoing, there were important particularities to be highlighted in this systematic review, such as the fact that mothers with previous breastfeeding experience over a period of more than six months had higher rates of self-efficacy^{19,26}. Ip et al.²⁹ and Henshaw et al.²⁸ agreed that AME decreases up to 06 months of age. While McCarter-Spaulding and Gore¹⁹ described that self-efficacy in breastfeeding may vary, depending on the culture or ethnicity of black women, indicating that for these women, appropriate educational approaches should be implemented. Therefore, in all the studies, it could be observed that the BSES scale (in its two variations) was an effective tool for predicting the duration of exclusive breastfeeding in primiparous or non-primiparous mothers. In addition, it was capable of identifying those who were at risk of practicing weaning before six months had elapsed. Furthermore, they showed that it was important for health professionals to use this tool when they were developing breastfeeding educational programs, to detect mothers at risk of practicing early weaning. They should also encourage mothers to be more aware of their performance while breastfeeding, which would result in increasing their confidence in breastfeeding.

Potential biases in the process of this review

There was no bias related to the year of publication because the scale was developed as from 1999, and therefore there was no study before this period. The selection involved articles published between 1999 and 2015. All the studies analyzed

were published in English, however a language bias was found in the article selection process: four publications were previously selected, but were not included in the final evaluation because they were written in languages other than those provided for in the inclusion criteria.

A confounding factor was the lack of articles analyzing self-efficacy in breastfeeding and the practice of SMA as the main outcome, without the presence of other aims in the study.

In addition, the scale applied in the postpartum period may also correspond to a bias, since there are differences between its application in the first gestation, and its application in mothers who have previous experience with breastfeeding. This is because in the latter case the mother already has greater perception of herself, and consequently, this interferes positively in her self-confidence.

One possible bias was the fact that the studies did not clearly indicate the association between the results of the scale scores and SMA until six months of age. Some evaluated only the mean value of the sample scores, while others did not present any data on the score. This information would be of extreme importance for a more detailed assessment of self-confidence, making it possible to conduct meta-analysis and improve the evidence of results.

Moreover, the decrease in the sample during the course of the study – a fact that could decrease the study validity - could also be considered a bias; especially in those that presented a loss greater than 30%.

The non-standardization of specific time intervals for scale application of the surveys included in this review was also seen as a bias, because this did not allow identification of the most appropriate time interval for applying the scale, and for recognizing mothers at risk of early abandonment of exclusive breastfeeding. There was a variation of between two and seven days of puerperium, and this may interfere in obtaining the results because, as previously reported in this review, the mother's contact with breastfeeding and the experience gained during this period clearly and significantly interfered with her perception about performing the practice and her self-confidence. Worth mentioning is that the period indicated in this review (from 2 to 7 days) was favorable for the application of these scales, and in all the studies there was a positive association between the confidence level and SMA at 6 months.

The results cannot be generalized to the whole population, due to the particularities and

methodological heterogeneity of each study included in this review.

Quality assessment of included studies

It was not possible to perform the meta-analysis of the results collected in this study. The evaluated articles did not provide enough statistical data, such as, for example: p-value, standard deviation, confidence interval, among others, for the above-mentioned purpose. Nevertheless, with the results described and analysis of the discussion in the studies, self-confidence was verified to be a factor that significantly influenced the practice of exclusive breastfeeding in 06 months postpartum.

During follow-up of cohort studies, sample loss of up to 10% is acceptable, because losses commonly occur due to changes in address and / or telephone, lack of interest in participating, illness and even due to death³⁰. Sample bias was seen in only one of the studies that presented a sample loss greater than 30%²⁸.

In three studies, over than 60% of mothers were observed to be capable of breastfeeding until 06 months, while other studies presented a percentage lower than 30% of mothers who were able to practice exclusive breastfeeding until the intended period^{19,28}. The low level of practicing EBM up to 06 months of age of the babies occurred nationally and globally, as several factors interfered with the process, including beliefs that should be discouraged by health professionals.

Another problem presented was information bias. In some of the studies, BSES / BSES-SF was applied in mothers who had previous experience of success or failure in breastfeeding, who frequently showed greater self-confidence, and consequently, a obtained significantly higher scores than mothers who had no previous experience 19,26,29.

Selection bias was also a flaw presented by some studies, in which the samples were composed of mothers of different nationalities or mothers with higher levels of schooling (e.g., analysis of only women with full higher education) or mothers identified according to their ethnicity. There were cases in which the authors described that the analyzed sample was insufficient for the comparison between the groups, because the data obtained by means of the mean scale scores were insufficient to obtain the desired result^{19,28}.

The authors who developed the BSES and BSES-SF scales^{16,17} proposed that they should

be self-applied and therefore the type of survey performed by all the studies of this review was presented as being a self-report. Nevertheless, in the qualitative scale proposed by this study, the researchers decided to retain the lack of quality for this question, since it is known that it can lead to the excess or lack of information on breast-feeding, thus influencing correct evaluation of the data²⁶.

Justification for exclusion

According to Burns³¹, the cohort study has the highest level of evidence and is less prone to presenting bias. A small number of cohort studies were found and included in the present study. This was because a minority of studies applied the BSES / BSES-SF scale which, in addition to the follow-up period of 6 months of exclusive breastfeeding recommended by the World Health Organizations, were the main objects of evaluation of this review of the literature. Thus, studies that did not have these two factors were excluded because they did not allow assessment of the mothers' self-confidence to practice breastfeeding.

Other factors for excluding studies were: the lack of results; not showing the relationship between the score value and breastfeeding, and being written in languages other than English, Portuguese and Spanish.

Level of evidence

The evidence obtained in this systematic review showed that mothers who have a high level of confidence in exclusive breastfeeding maintain the practice for longer periods than those who had lower scores. However, it was not possible to confirm whether the application of BSES / BSES-SF in the postpartum period influenced the achievement of higher scores, since the experience of mothers with the practice of breastfeeding was believed to have a positive or negative influence on the practice of exclusive breastfeeding, resulting in scores differing from those that would be obtained if the scale were applied in the prenatal period.

There was heterogeneity in the methodology applied in the studies and lack of blind evaluation, since the majority obtained information by means of self-reports, a prominent factor for the occurrence of information bias. In addition, the absence of control for confounding factors, such as psychological variables and self-efficacy in breastfeeding in the prenatal period, which also

interfered with the practice of exclusive breastfeeding, should be pointed out. Non-inclusion of multiparous mothers in the sample would be a good strategy for future studies.

The evidence reported in this review is at present being used to compile more recent results to guide the elaboration of a clinical course on identifying mothers at risk for early weaning, even considering their limitations, until new observational or experimental cohort studies are conducted. It is noteworthy that no good quality randomized clinical trials on the subject were found to support the conclusions. This gap should be filled to provide better results to establish association between self-confidence in breastfeeding and the practice of exclusive breastfeeding until babies are 06 months of age.

Conclusion

The results of the studies that comprised this systematic review demonstrated that women's self-confidence was associated with the longer duration of exclusive breastfeeding, but it was not possible to generalize the results due to the heterogeneity of the populations studied.

It is interesting to emphasize the importance of the health professional in recognizing maternal self-efficacy (whether the mothers are primiparous or not) and developing individualized strategies to strengthen or even build their confidence in the practice of breastfeeding in a correct and exclusive manner, since low confidence may often be related to emotional adjustments, such as postpartum depression, and consequently, the occurrence of early weaning.

The BSES and BSES-SF scales have been recognized as having the potential to be practical, valid and reliable measures of the self-efficacy of mothers who may be at risk for premature termination of exclusive breastfeeding. Moreover, their use can greatly facilitate the activities of health professionals.

Guidelines for future research

Cohort studies and randomized clinical trials with longitudinal data should be conducted on the relationship between self-efficacy in breast-feeding and duration of exclusive breastfeeding. It is necessary to conduct research in the prenatal period in order to identify mothers at risk for early abandonment of the practice of exclusive breastfeeding.

Collaborations

IS Rocha - Collection, Interpretation and analysis of data, preparation and writing of the manuscript, critical review, and final approval; NB Rocha- Project and study design, study orientation, interpretation and analysis of data, preparation and writing of the manuscript, critical review, and final approval; M Fujimaki, LF Lolli and A Gasparetto - Data interpretation and analysis, critical review, and final approval.

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